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K031740

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510(k) Summary of Safety and Effectiveness

May 30, 2003

Submitter

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 530-7500
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Contact: Mr. James W. Sandberg, Director of Regulatory Affairs & Compliance Engineering

Device Name

Trade Name: Vital Signs Monitor, Model 53000 Series
Common Name: Vital Signs Measurement Device

Classification Name: Noninvasive Blood Pressure Measurement System, 21CFR870.1130, April 1,2002. The VSM model 53000 Series also offers a Pulse Oximetry channel (SpO_2) – reference 21CFR870-2700, April 1, 2002, and a patient temperature channel, Clinical electronic thermometer, reference 21CFR880.2910, April 1, 2002.

Classification: Class II

Predicate Devices

The predicate devices for the model 53000 Series monitors are the

- Welch Allyn CVSM vital signs monitors model 52STP, K951193, and
- Protocol Systems Propaq Encore 200 Series, K951246, and
- Nellcor Puritan Bennett Pulse Oximeter module MP506 cleared with Pulse Oximeter Model N-550 K021090, and
- Welch Allyn SureTemp™ Plus, K030580.

Device Description

The model 53000 Series of monitors are intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, body temperature, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature in normal and axillary modes of neonatal, pediatric and adult patients.

The most likely locations for patients to be monitored are general med/surg. floors, general hospital and alternate care environments. This device is available for sale only upon the order of a physician or licensed health care professional.

Indications for Use

The model 53000 Series of monitors are intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, body temperature, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature in normal and axillary modes of neonatal, pediatric and adult patients.

The most likely locations for patients to be monitored are general med/surg. floors, general hospital and alternate care environments. This device is available for sale only upon the order of a physician or licensed health care professional.

Technological Comparison to the Predicate Devices

It is Welch Allyn Protocol's conclusion that the vital signs monitors model 53000 Series are substantially equivalent to the Welch Allyn Tycos vital signs monitor CVSM Model 52SP-E1, the Protocol Systems Propaq Encore 200 Series monitors, the Nellcor Puritan Bennett Pulse Oximeter, Model OxiMAX N-550, and the Welch Allyn Clinical electronic thermometer, Model SureTemp™ Plus.

- The **noninvasive blood pressure** measurement specifications and performance are equivalent to the Welch Allyn Tycos CVSM monitor and the Protocol Systems Propaq Model 200 Series monitors, and
- The **pulse rate** specifications and performance derived from either noninvasive blood pressure or SpO_2 are equivalent to the Welch Allyn Tycos CVSM monitor, the Protocol Systems Propaq, Model 200 Series monitors, and the Nellcor Puritan Bennett Pulse Oximeter Model N-550, and
- The **SpO_2** specifications and performance are equivalent to the Nellcor Puritan Bennett Model N-550 Pulse Oximeter, and
- The Welch Allyn **Clinical temperature** meter SureTemp™ Plus is the same temperature module used in the Welch Allyn model 53000 Series monitors.

Summary of Performance Testing

The Welch Allyn vital signs monitors, model 53000 Series will be tested in accordance with the Test Plan / Report, #831-0719-00, and Clinical Validation Report #831-0752-00 included with the submission using production equivalent units prior to release to market.

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Welch Allyn Protocol's product development procedure. Welch Allyn Protocol's Quality System conforms to 21CFR820 and is certified by TÜV Product Service to ISO 9001, EN 46001 and ISO 13485.

Conclusions

As stated above, Welch Allyn Protocol's conclusion is that the vital signs monitor Model 53000 Series are safe and effective and comply with the appropriate medical device standards and are substantially equivalent to the earlier identified predicate devices.

This *510(k) Summary of Safety and Effectiveness* may be copied and submitted to interested parties as required by 21CFR807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2003

Welch Allyn Protocol, Inc.
c/o Mr. James W. Sandberg
Director of Regulatory Affairs & Compliance Engineering
8500 S.W. Creekside Place
Beaverton, OR 97008-7107

Re: K031740
Trade Name: VSM Vital Signs Monitor, Model 53000 Series
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA
Dated: May 30, 2003
Received: June 4, 2003

Dear Mr. Sandberg:

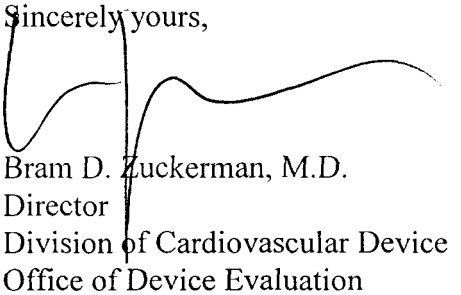
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031740

INDICATIONS FOR USE

Applicant:

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 530-7500
Fax: (503) 526-4901

510(k) Number:_____

Device Name: Vital signs monitors, model 53000 Series

Indications for Use:

The VSM series of monitors are intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, body temperature, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature in normal and axillary modes of neonatal, pediatric and adult patients.

The most likely locations for patients to be monitored are general med/surg. floors, general hospital and alternate care environments. This device is available for sale only upon the order of a physician or licensed health care professional.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascul.

510(k) Number K031740